

Serial No. 10/783,268

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1. (Withdrawn) A pharmaceutical composition comprising a combination of at least one quinolinic antimalarial compound, and at least one of an inhibitor of the Human Immunodeficiency Virus (HIV) protease or pharmaceutically acceptable salts thereof, and optionally a pharmaceutically acceptable carrier.
2. (Withdrawn) The composition of claim 1, wherein said quinolinic antimalarial compound is selected from the group consisting of Chloroquine (CQ), Hydroxycloquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof.
3. (Withdrawn) The composition of claim 2, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof.
4. (Withdrawn) The composition of claim 1, further comprising at least one nucleosidic inhibitor of the HIV Reverse Transcriptase (NRTI).
5. (Withdrawn) The composition of claim 4, wherein said NRTI is selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emitricitabine (FTC), amdoxovir (DAPD), and combinations thereof.
6. (Withdrawn) The composition of claim 1, wherein the composition comprises from about 0.8 % to about 15 % by weight of said quinolinic antimalarial compound.

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7. (Withdrawn) The composition of claim 1, wherein the composition comprises from about 34 % to about 75 % by weight of said quinolinic antimalarial compound.

8. (Withdrawn) The composition of claim 1, wherein the composition comprises from about 0.8 % to about 33 % by weight of said quinolinic antimalarial compound.

9. (Withdrawn) The composition of claim 1, wherein the composition comprises an amount of said inhibitor of the HIV protease of the combination sufficient to achieve a blood plasma concentration of from about 10 nanomolar to about 30 micromolar.

10. (Withdrawn) The composition of claim 9, wherein the composition comprises an amount of said quinolinic antimalarial compound of the combination sufficient to achieve a blood plasma concentration of from about 0.005 micromolar to about 6 micromolar.

11. (Withdrawn) The composition of claim 1, wherein the composition comprises ritonavir at a dose of from about 1 mg per kg of body weight to about 150 mg per kg of body weight.

12. (currently amended) A method of treating ~~or preventing~~ malaria in humans comprising administering to a patient, in need thereof, a therapeutically effective amount of a composition comprising:

at least one of the inhibitors of the HIV protease, or pharmaceutically acceptable salts thereof, selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof, in an amounts that are is therapeutically effective to inhibit the growth of *Plasmodium sp.*

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13. (Cancelled)

14. (Currently amended) The method of claim 12, wherein the therapeutically effective amount of said inhibitor of the HIV protease ~~of the combination~~ comprises ritonavir at a dose of from about 1 mg per kg of body weight to about 150 mg per kg of body weight.

15. (Withdrawn) A pharmaceutical kit for treating or preventing a physiological condition associated with HIV infection, malaria or both, said kit comprising a plurality of containers, wherein at least one of said containers contains at least one quinolinic antimalarial compound or a pharmaceutically acceptable salt thereof, and one other of said plurality of containers contains at least one inhibitor of the HIV protease or a pharmaceutically salt thereof, wherein the amounts of said quinolinic antimalarial compound, and said inhibitor of the HIV protease in said containers consist of therapeutically effective amounts of said quinolinic antimalarial compound and said inhibitor of the HIV protease.

16. (Withdrawn) The kit of claim 15, wherein said quinolinic antimalarial compound is selected from the group consisting of Chloroquine (CQ), Hydroxycloquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof.

17. (Withdrawn) The kit of claim 15, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof.

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18. (Withdrawn) The kit of claim 15, wherein said pharmaceutical kit further comprises at least one container containing at least one nucleosidic inhibitor of the HIV Reverse Transcriptase (NRTI).

19. (Withdrawn) The kit of claim 18, wherein said NRTI is selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emtricitabine (FTC), amdoxovir (DAPD), and combinations thereof.

20. (Withdrawn) The kit of claim 15, wherein the therapeutically effective amount of said quinolinic antimalarial compound of the combination is from about 0.8 % to about 15 % by weight.

21. (Withdrawn) The kit of claim 15, wherein the therapeutically effective amount of said quinolinic antimalarial compound of the combination is from about 34 % to about 75 % by weight.

22. (Withdrawn) The kit of claim 15, wherein the therapeutically effective amount of said quinolinic antimalarial compound of the combination is from about 0.8 % to about 33 % by weight.

23. (Withdrawn) The kit of claim 15, wherein the therapeutically effective amount of said inhibitor of the HIV protease of the combination is sufficient to achieve a blood plasma concentration of from about 10 nanomolar to about 30 micromolar.

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24. (Withdrawn) The kit of claim 23, wherein the therapeutically effective amount of said quinolinic antimalarial of the combination is sufficient to achieve a blood plasma concentration of from about 0.005 micromolar to about 6 micromolar.

25. (Withdrawn) A pharmaceutical kit for treating or preventing a physiological condition associated with malaria, said kit comprising a plurality of containers, wherein at least one of said containers contains at least one of an inhibitor of the HIV protease or a pharmaceutically salt thereof, wherein the amounts of said inhibitor of the HIV protease in said containers consist of a therapeutically effective amount to at least partially inhibit the growth of *Plasmodium sp.*, and said containers optionally contain a pharmaceutically acceptable carrier.

26. (Withdrawn) The kit of claim 25, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, and combinations thereof.

27. (Withdrawn) The kit of claim 25, wherein the therapeutically effective amount of said inhibitor of the HIV protease comprises ritonavir at a dose of from about 1 mg per kg of body weight to about 150 mg per kg of body weight.

28. (Currently amended) A method of treating ~~or preventing~~ HIV infection, malaria, or both, in humans comprising administering to a patient, in need thereof, a composition comprising a combination of:

at least one quinolinic antimalarial compound selected from the group consisting of Chloroquine (CQ), Hydroxychloroquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof and

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at least one of an inhibitor of the HIV protease selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof, or pharmaceutically acceptable salts thereof, in amounts that are synergistic in therapeutic efficacy to inhibit the growth of *Plasmodium sp.*, the competent replication and infectivity of the Human Immunodeficiency Virus or both.

29. (Cancelled)

30. (Cancelled)

31. (Original) The method of claim 28, wherein the combination also includes at least one nucleosidic inhibitor of the HIV Reverse Transcriptase (NRTI).

32. (Original) The method of claim 31, wherein the NRTI compound is selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emtricitabine (FTC), amdoxovir (DAPD), and combinations thereof.

33. (Original) The method of claim 28, wherein the therapeutically effective amount is from about 0.8 % to about 15 % by weight of said quinolinic antimalarial compound.

34. (Original) The method of claim 28, wherein the therapeutically effective amount is from about 34 % to about 75 % by weight of said quinolinic antimalarial compound.

35. (Original) The method of claim 28, wherein the therapeutically effective amount is from about 0.8 % to about 33 % by weight of said quinolinic antimalarial compound.

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36. (Original) The method of claim 28, wherein the therapeutically effective amount of said inhibitor of the HIV protease of the combination is sufficient to achieve a blood plasma concentration of from about 10 nanomolar to about 30 micromolar.

37. (Original) The method of claim 36, wherein the therapeutically effective amount of said quinolinic antimalarial compound of the combination is sufficient to achieve a blood plasma concentration of from about 0.005 micromolar to about 6 micromolar.

38. (Withdrawn) A method of limiting the spread of HIV infection, malaria or both, comprising the step of exposing a cell population infected with HIV, *Plasmodium sp.* or both, to a composition comprising a combination of:

at least one quinolinic antimalarial compound and at least one of an inhibitor of the HIV protease, or pharmaceutically acceptable salts thereof, in amounts that are additive or synergistic to inhibit the growth of *Plasmodium sp.*, the competent replication and assembly of the Human Immunodeficiency Virus or both.

39. (Withdrawn) The method of claim 38, wherein said quinolinic antimalarial compound is selected from the group consisting of Chloroquine (CQ), Hydroxycloquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof.

40. (Withdrawn) The method of claim 38, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, ataznaavir, TMC-114, and combinations thereof.

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41. (Withdrawn) The method of claim 38, wherein the composition further comprises at least one nucleosidic inhibitor of the HIV Reverse Transcriptase (NRTI).

42. (Withdrawn) The method of claim 41, wherein the NRTI compound is selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emtricitabine (FTC), amdoxovir (DAPD), and combinations thereof.

43. (Withdrawn) The method of claim 38, wherein the therapeutically effective amount of said inhibitor of the HIV protease of the combination is sufficient to achieve a blood plasma concentration or a cell culture medium concentration of from about 10 nanomolar to about 30 micromolar.

44. (Withdrawn) The method of claim 38, wherein the therapeutically effective amount of said quinolinic antimalarial of the combination is sufficient to achieve a blood plasma concentration or a cell culture medium concentration of from about 0.005 micromolar to about 6 micromolar.

45. (Withdrawn) The method of claim 38, wherein the therapeutically effective amount is from about 0.8 % to about 75 % by weight of said quinolinic antimalarial compound.

46. (Withdrawn) A method of limiting the spread of malaria comprising the step of exposing a cell population infected with *Plasmodium sp.* to a composition comprising:

at least one inhibitor of the HIV protease, or pharmaceutically acceptable salts thereof, in amounts that are effective to inhibit the growth of *Plasmodium sp.*



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47. (Withdrawn) The method of claim 46, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof.

48. (Withdrawn) The method of claim 46, wherein the effective amount of said inhibitor of the HIV protease of the combination ranges from about 0.5 micromolar to 30 micromolar.

49. (Withdrawn) A method of substantially conferring antiretroviral drug-sensitivity to substantially drug-resistant HIV strains comprising the step of administering to an HIV infected human or exposing a cell population infected with HIV to a composition comprising:

at least one quinolinic antimalarial compound or pharmaceutically acceptable salts thereof, in amounts that are effective to substantially confer at least partial sensitivity to at least one inhibitor of HIV protease, with or without at least one NRTI and/or antiretroviral drugs belonging to other classes.

50. (Withdrawn) The method of claim 49, wherein said quinolinic antimalarial compound is selected from the group consisting of Chloroquine (CQ), Hydroxycycloquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof.

51. (Withdrawn) The method of claim 49, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof.

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52. (Withdrawn) The method of claim 49, wherein the NRTI compound is selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emtricitabine (FTC), amdoxovir (DAPD), and combinations thereof.

53. (Withdrawn) The method of claim 49, wherein the therapeutically effective amount of said quinolinic antimalarial of the combination is sufficient to achieve a blood plasma concentration or a cell culture medium concentration of from about 0.05 micromolar to about 1 micromolar.

54. (Withdrawn) A method of substantially conferring antimalarial drug-sensitivity to substantially drug-resistant *Plasmodium falciparum* strains comprising the step of administering to a human subject or exposing a cell population infected with *P. falciparum* to a composition comprising:

at least one inhibitor of HIV protease or pharmaceutically acceptable salts thereof, in amounts that are effective to substantially confer at least partial sensitivity to at least, one quinolinic antimalarial compound.

55. (Withdrawn) The method of claim 54, wherein said inhibitor of the HIV protease is selected from the group consisting of indinavir (IDV), ritonavir (RTV), saquinavir (SQV), nelfinavir (NFV), lopinavir (LPV), amprenavir (APV), fosamprenavir, tipranavir, atazanavir, TMC-114, and combinations thereof.

56. (Withdrawn) The method of claim 54, wherein said quinolinic antimalarial compound is selected from the group consisting of Chloroquine (CQ), Hydroxycloquine (HCQ), Mefloquine (MQ), Quinine (Q), and combinations thereof.

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57. (Withdrawn) The method of claim 54, including the contemporary administration of an NRTI compound selected from the group consisting of zidovudine (AZT or ZDV), lamivudine (3TC), abacavir (ABC), zalcitabine (ddC), didanosine (ddI), stavudine (d4T), tenofovir (TDF) emtricitabine (FTC), amdoxovir (DAPD), and combinations thereof.

58. (Withdrawn) The method of claim 54, wherein the therapeutically effective amount of said inhibitor of the HIV protease of the combination is sufficient to achieve a blood plasma concentration or a cell culture medium concentration of from about 0.5 micromolar to about 30 micromolar.